ARIZONA DEPARTMENT OF HEALTH SERVICES

OFFICE OF CHRONIC DISEASE PREVENTION & NUTRITION SERVICES

LABORATORY PROCEDURE MANUAL

5th Edition
2007

Acknowledgments

Several people contributed their expertise, time and energy to the development of this biochemical assessment manual. Without their recommendations and efforts, updating this manual would not have been possible. A sincere thank you is owed to each of them.

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Chapter 1. Introduction

Purpose

The purpose of the Arizona Department of Health Services, Office of Chronic Disease prevention & Nutrition Services Laboratory Procedure Manual is to provide guidance to local agency staff while performing hemoglobin tests used in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), the Commodity Supplemental Food Program (CSFP) and the Community Nutrition Programs. The manual is designed to be user-friendly.

Arizona WIC has transitioned to HemoCue® 201 DM systems. HemoCue® 201 DM systems bring Data Management capabilities to the HemoCue® product line. It offers faster data availability, better quality control, increased regulatory compliance and improved administration. HemoCue® 201 DM systems ensure the authorized and appropriate use of HemoCue® analyzers. This data is then transmitted to the Arizona Department of Health Services allowing for improved statistical management. Procedural updates throughout the manual have also been made to reflect the omission of the old B-Hemoglobin system to the new HemoCue® 201 DM systems.

Here is what you will find in the revised fifth edition of the lab manual:

Quality Control

The fourth edition chapter, *How to Run a HemoCue® Control*, has been omitted from the revised fifth edition as the new HemoCue Hb 201 DM analyzer has an internal electronic "self test." Every time the analyzer is turned on, it automatically verifies the performance of the optronic unit. The upgrade to the DM system also discontinues the use of the Laboratory Client Log by the local agencies.

Administration of HemoCue® DM Equipment for the Local Agencies

This section includes procedures for receiving and inventory of new or loaner equipment from ADHS or directly from HemoCue® as well as administration of the users.

Problems With An Analyzer or Docking Station

This section includes troubleshooting guidance for the most commonly occurring error messages with the data management equipment and technical complications.

Chapter 2. Safety

Universal Precautions

In 1991, the Occupational Safety and Health Administration (OSHA) published the Occupational Exposure to Bloodborne Pathogens Standard. The purpose of the standard is to minimize, if not eliminate, occupational exposure to bloodborne pathogens and, if followed, should keep you safe when you work in your lab area. The standard outlines necessary engineering and work practice controls, as well as requiring the availability and use of personal protective equipment (PPE).

One section of the standard deals with "Universal Precautions (UP)." This term is simply an approach or strategy designed to keep you safe when you work with blood or other bodily fluids. Under UP, the blood and certain bodily fluids of *all* individuals are considered potentially infectious. Standardized practices focus on treating every sample of blood as if it were disease-infected. Handle all human blood and certain human bodily fluids as if they were known to be infected with Human Immuno-deficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or other bloodborne pathogens. Ask your supervisor if you have further questions.

These precautions are intended to prevent the transmission of infectious bodily fluids through parenteral routes such as mucous membranes and non-intact skin.

In 2001, the standard was revised to conform to the Needlestick Safety and Prevention Act. The act directed OSHA to revise the Bloodborne Pathogens (BBP) Standard in the areas of the Exposure Control Plan with new record-keeping requirements, employee input for work practice controls and modification of definitions of engineering controls.

Personal Work Practices

To comply with the OSHA standard, a written exposure control plan must be in place at each WIC clinic/site. The plan includes a copy of local policies and procedures for employee safety and a procedure for reporting accidents. Your manual should be kept close at hand and you should adhere to all of the practices as suggested in this manual. Each local agency will develop blood-borne pathogen information and training programs for all employees.

For your personal protection, follow these guidelines:

- Get a Hepatitis B vaccination.
- Do not allow or bring food, drinks or medication into technical work areas.
- Do not touch your face, apply makeup or handle contact lenses while in work areas where there is a reasonable likelihood of occupational exposure.
- Food and drink shall not be kept in refrigerators, freezers, shelves or on countertops where blood or other potentially infectious materials are present.

Safety Continued

Personal Work Practices Continued	• The single most important means of preventing the spread of infection is handwashing. Wash your hands: ✓ At the beginning and end of your shift ✓ Before a skin puncture and after removing your gloves ✓ After weighing unclothed infants ✓ After touching contaminated objects or using restroom facilities ✓ After making contact with your eyes, nose or mouth ✓ Before and after eating, drinking or handling food • Cover any break in the skin with a bandage. • Wear disposable gloves when there is a possibility of contact with bloodborne pathogens. • Use new gloves for every blood draw, even if participants are from the same family. • Take advantage of all training offered by your employer. Your employer has considered the risks of contamination and established its own standards based on "reasonable risk." • Note: Your local agency may determine whether masks, eye protection devices such as goggles or glasses with solid side shields, or chin length face shields, should be worn. • Usually, protective devices for eyes, nose or mouth are worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and contamination may be anticipated. It is generally accepted that the HemoCue® test for hemoglobin does not splatter or spray blood. **Warning!** **If blood touches your skin or hair, wash the area with soap and water, and tell your supervisor immediately.** **If blood splashes into your eyes, flush them with water. Contact a physician.** **If you are accidentally stuck by a contaminated lancet, contact your supervisor. Arrange to see a licensed healthcare provider for a medical evaluation and counseling and to be tested for Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).**

Safety Continued

Worksite Protection

- Recommended Lancet for Finger Punctures (children >18 months and adults): Single-Use (needle is not able to be extended a second time) Capillary Blood Sampling Device, 2.25mm needle.
- Recommended Lancet for Heel Punctures (infants 9-18 months and children with very small fingers): Single-Use Capillary Blood Sampling Device, 1.8mm needle.
- Clean the work site at the beginning and end of each workday or after any contact with blood or other potentially infectious materials.
- Use a prepared bleach solution (see below) or an EPA-registered disinfectant that is effective as a tuberculocidal and kills Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).
- In order to decontaminate contaminated work surfaces. Be sure to:
  1) Wear clean gloves
  2) Completely remove all blood before applying the disinfectant
  3) Leave the surface wet with the disinfectant for 30 seconds for HIV and 10 minutes for HBV
  4) Dispose of the infectious waste in accordance with federal, state, or local regulations (see page seven)
- EPA-registered tuberculocidal disinfectants and bleach solutions are appropriate for removing blood or other potentially infectious materials on surfaces and instruments. The Material Safety Data Sheet (MSDS) for commercial disinfectants must be posted in the clinic and all employees must be aware of its location.

Preparation and Storage of Bleach Solution

- Prepare a fresh bleach (5.25% sodium hypochlorite) solution weekly.
- To prepare a 10% bleach solution, mix 1 part household bleach with 9 parts tap water.
- Store at room temperature in an opaque plastic bottle labeled "10% Bleach." The date of preparation and the expiration date should be clearly marked on the outside.
  Note: The expiration date is at the end of the seventh calendar day.
- Store out of the reach of children.

Safety Continued

Disposal of Laboratory Waste and Supplies

- Discard all contaminated sharps, i.e.: retractable lancets & cuvettes, in special receptacles usually referred to as "sharps" containers. There are a variety of styles, and all are clearly marked with a biohazard symbol (see figure to the left). The container must be rigid, puncture-resistant, leak-proof, and disposable with a locking lid.

- Regardless of whether or not lancets contain safety features, such as retractable blades, all used lancets and other sharp objects must be disposed of immediately in a "sharps" container. When this container is filled to the acceptable level, it must be properly disposed of as biohazardous waste.

- Throw away other potentially infectious trash that is saturated with blood in a red, plastic biohazard bag. Find out from your supervisor how to handle biohazardous waste since it must be decontaminated before it can be disposed of in a landfill.

- All waste that is saturated and dripping with blood must be
  - ✓ Sterilized
  - ✓ Incinerated or
  - ✓ Chemically disinfected prior to mixing and disposing with ordinary waste.

- Waste, such as lint-free tissue, alcohol preps, gloves, bandages & wrappers, that contains blood but is not dripping, can be discarded in a regular trash bag if there are no means for biohazard waste disposal. Best Practice states it should be disposed of in a biohazard bag.

- Keep the biohazard bag and all trash out of the reach of children.

Chapter 3. Information About Blood Testing

Type of Blood Tests	There are many components of blood, and many tests are done for diagnostic purposes. The only blood test that will be addressed in this manual is hemoglobin.
Hemoglobin Testing	WIC staff conduct hemoglobin tests to screen and assess the participant's nutritional status. The test measures the amount of hemoglobin in the red blood cells. The hemoglobin test is performed because it is a quick screening tool for iron deficiency anemia.
Anemia	A low hemoglobin test result indicates the possibility of iron deficiency anemia. Anemia is a condition in which there are low levels of iron in the blood, with symptoms such as poor appetite, tiredness, weakness, developmental delays and learning problems present. It is the most prevalent risk factor of WIC participants. In the WIC program, a low hemoglobin level is most often treated with education and foods high in iron and Vitamin C. Referral for high-risk counseling and medical treatment may also be indicated. (Appendix A)
Anemia Cutoffs	Arizona uses the 1998 Centers for Disease Control and Prevention (CDC) Guidelines for anemia cutoffs (Appendix B). These cutoffs are also recommended by the Institute of Medicine as an acceptable reference. The cut-off values for anemia vary with altitude, age, sex, smoking status and stage of pregnancy.
Correct Values	You, as a health professional/paraprofessional, have an important responsibility for correctly assessing values which may determine whether or not a person is eligible for the WIC Program. The values also determine the type of counseling and referral a participant receives.
Training	The Local Agency Director or her designee is responsible for ensuring the training, monitoring and supervision of the staff members who perform laboratory collection and analysis. Training must be adequate to meet the Clinical Laboratory Improvement Amendments (CLIA '88) regulations & follow the National Committee for Clinical Laboratory Standards (NCCLS) H4-A4 guidelines.

Information about Blood Testing Continued

Authorization

A Letter of Authorization, which lists the individuals qualified to obtain and analyze laboratory samples, as well as the dates when they were certified, will be maintained on file by each local agency. The letter also needs to contain dates for which it is valid (i.e.: October 1, 20XX - September 30, 20XX). In addition, a CLIA "Certificate of Waived Testing" is required.

Work Area

Select a work area for collection of the laboratory specimen.
An ideal work area:

- Is clean
- Ensures client and staff safety
- Has a surface which is smooth, free of cracks, and washable
- Ensures patient privacy
- Is away from noise and confusion
- Has a chair and table

Hemoglobin Measuring Machines

HB 201 DM®

The HemoCue® DM system consists of a docking station for network communication and an analyzer, a portable instrument with a sliding cuvette holder and display screen. The analyzer measures the amount of hemoglobin contained in a blood sample. The measurement takes up to 60 seconds and is expressed as grams per deciliter or g/dl. After reading the sample, the value will remain displayed on the screen for five minutes.

Daily care of the hemoglobin analyzer is explained in Chapter 4 of this manual. Troubleshooting guidelines and detailed cleaning instructions are also found in the HemoCue Hb 201 DM Analyzer and HemoCue DM Docking Station Reference Manual and the HemoCue Hb 201 DM Analyzer Instructions for Use available in each clinic.

Storage of Cuvettes

- Store cuvettes at room temperature. Do not expose to any direct heat source.
- Label the vial with the date on which it is opened.
- Label the vial with the date on which the contents of the vial expire (vial expires 90 days after opening). Note: an unopened vial of cuvettes has a two-year shelf life from the date of manufacture.
- Snap the vial cap closed each time a cuvette is removed. Never leave the cap partially open. The cuvettes are very sensitive to humidity and moisture. Remove one cuvette at a time for testing.

Chapter 4. Daily Steps for Performing Hemoglobin Tests

Identify Client

Assure that the consent boxes are checked and the client or authorized representative has signed and dated the consent/release form.

Explain Procedure

Explain the procedure to the client or authorized representative in simple terms. Reassure them.

Example

"I am going to make a little poke in your finger/heel to get a few drops of blood to put the blood into this little container. Then I am going to put it into this machine to find out how much iron it has in it." Be honest with him/her. If he/she asks if it may hurt, answer, "Yes, it may hurt a little."

Don't ever say, "No, it won't hurt."

Assemble Supplies

- HemoCue® Analyzer
- Gloves
- Alcohol prep pads
- Sterile lancets
- Lint-free tissues/KimWipes® or Gauze pad
- Closed vial of cuvettes
- Bandages (not for children under age 2)
- Sharps container
- Biohazard bag
- 10% bleach solution or disinfectant
- Soap and water, alcohol-based hand cleanser or hand wipes

Cleanse/Glove Hands

Wash hands with soap and water or cleanse with an alcohol-based hand cleanser or hand wipes and put on gloves.

CHANGE GLOVES BETWEEN EVERY CLIENT!

Daily Steps for Performing Hemoglobin Tests Continued

Position Client

For infants one year of age and younger, a seated adult holds the infant over adult's shoulder or baby lies face-down across lap for heelstick.
NOTE: The heel site is recommended for infants 9-12 months of age to prevent possible bone or nerve damage in areas where there is less flesh. If a child 12-18 months of age has small fingers it is at the staff's discretion to continue with a heelstick. Children 18 months of age and older should not receive a heelstick.

For everyone else, seat client and extend arm with palm up.

♥ BE SURE THAT PUNCTURE SITE IS LOWER THAN THE HEART.

Choose Site

For infants, use either side of the plantar (bottom) surface of the heel when the baby is held over caregiver's shoulder. Never puncture the back curvature of the heel.
For everyone else, seat the participant or ask someone to help with a child. For instance, the caregiver may hold the child in his/her lap using both arms to keep the child still while you perform the procedure.
Have the client extend his/her arm with the hand lower than the heart and palm facing up. Use the middle or ring finger, but choose a finger that doesn't have a ring on it.

Warm the Site (If Necessary)

The site should not be cold, blue, swollen or calloused.
If cold, warm the site by holding it in your hands, rubbing it for a minute, or by having the participant wash their hands vigorously with warm running water and soap or gently shake her hands.

Cleanse the Site

Cleanse the site thoroughly with an alcohol pad.
Wipe the site with a tissue or lint-free wipe. Be sure skin is *dry*.
Note: Pooled alcohol at the puncture site will dilute and hemolyze the blood, giving a lower reading, if the skin surface is not dried completely.

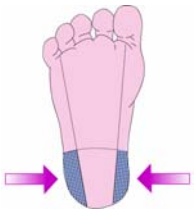
Hold the Site

For infants, position the foot below the infant's heart. Encircle the heel by wrapping the index finger around the arch and the thumb around the bottom of the heel (see figure to the left). Grasp the heel or finger firmly between your thumb and index finger using your thumb in a gentle rocking movement.
For everyone else, lightly press the finger from the closest knuckle to the tip in a rolling motion to stimulate the flow of blood to the sampling point.
WHAT *NOT* TO DO:
Do not touch the prepared site after cleaning. Do not "milk" the finger to speed the process. Squeezing or milking dilutes the blood and gives a false low reading.

Daily Steps for Performing Hemoglobin Tests Continued

Puncture

IMPORTANT: **If the lancet is blade-shaped, it should be placed perpendicularly to the whorls of the fingerprint/footprint so the blood is more easily collected into the cuvette.**



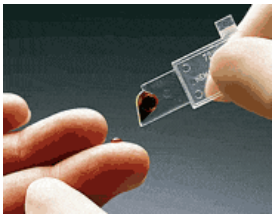
Create a firm surface where you are going to puncture by pulling the skin taut or tight with your index finger near the first joint of the finger on the client's hand.

For infants, 9-18 months of age or children with very small fingers, puncture only on the medial or lateral side of the bottom surface of the heel. See figure to the left.

Do not puncture the foot if there are bruises, abrasions or sloughing skin present.

For everyone else, children > 18 months of age and adults, puncture the side of the fingerpad nearest the thumb in one continuous motion using a retractable lancet. This will allow for easy blood collection. Puncturing on the side of the fingerpad is recommended and will hurt less than on top of the fingerpad since there are less nerve endings. The finger should be facing upwards upon puncture.

Fill the Cuvette



To ensure accuracy, you must wipe away the first two to three drops of blood. This will stimulate spontaneous blood flow, resulting in a better sample. If necessary, press gently again with thumb and forefinger until another drop of blood appears. Avoid "milking." **Do not touch the heel or finger at the site of puncture.**

All drops should be large enough so they "sit" on top of the heel or finger like a bead. Ensure that the drop of blood is big enough to fill the entire cuvette, including the tip. Touch the tip of the cuvette, pointing downward, into the middle of the blood drop so the cuvette touches the skin. Allow the cuvette to fill in one step. The cuvette will fill itself automatically. Never "top off" the cuvette if it doesn't fill in the first swipe.

Daily Steps for Performing Hemoglobin Tests Continued

Fill the Cuvette Continued

Wipe excess blood off the flat outside surfaces of the cuvette.
Keep it at a 45^{o} angle. Be careful not to touch the open-ended tip so that blood is not pulled back out of the cuvette.

Example
Using a gauze pad or lint-free wipe, "swipe" the cuvette as if you were sharpening a knife to remove any excess blood from the outside surfaces. Avoid the open "slit" of the cuvette with the gauze or wipe.

If the cuvette does not fill completely on the first try, or if air bubbles are visible, discard the cuvette, wipe the puncture site and allow a new, larger bead of blood to form before collecting into the cuvette again.

Measuring Hemoglobin Value

Turn the analyzer on and enter the 5-digit user ID number. Select patient test by touching the cuvette icon. Enter the client ID number.

Note: If the incorrect client ID # is entered in the analyzer, document the data entry error on the entry error log maintained in the local clinic (Appendix E).

Within 10 minutes of filling the cuvette, place it in its holder and gently push the holder into the analyzer with two fingers. When closed, the analyzer will automatically start the measuring procedure and the result will appear on the display.

Seal and Bandage Site

Place dry gauze or lint-free tissue over the puncture site and apply gentle pressure until the wound is clotted. Elevating the hand or foot above the level of the heart will help to stop the blood flow. Apply the bandage.

Note: Do not use bandages on the finger of a child less than two years of age to prevent potential ingestion and choking.

When to Run a Second Test

Occasionally, a second test must be run, such as when the displayed hemoglobin value is outside the "Nutritionist" range (Appendix B). A second sample must be taken from a different site, preferably a finger on the other hand. The higher of the two hemoglobin values is entered into the AIM computer system and should also be used for referral purposes.

Example
A 6.9 g/dl reading is obtained from an 18-month-old. The second reading is 8.5 g/dl. Record 8.5 g/dl, counsel and write this higher value on the referral form to the medical provider.

Daily Steps for Performing Hemoglobin Tests Continued

Cleanse Surface

If any blood spills on the HemoCue® Analyzer, work surfaces or skin, clean with a 10% bleach solution or disinfectant spray immediately.

Disposal of Supplies

- Throw away any paper wrappers, alcohol preps, gauze, lint-free tissues, gloves and other supplies which are not saturated and dripping with blood in a wastebasket.
- Throw away any supplies that are saturated and dripping with blood in the red biohazard bag. If your gloves are contaminated with blood, turn the gloves inside out while taking them off and place in the biohazard bag with the other supplies.
- Throw away all lancets and used cuvettes in the sharps container.

Remove Gloves and Wash Hands

Remove and discard gloves after each client and after handling contaminated waste. Clean hands with soap and water, alcohol-based hand cleanser or hand wipes if water is not available. Antiseptic hand cleanser, in conjunction with clean cloth/paper towels or antiseptic towelettes, are examples of acceptable alternatives to running water. However, when these types of alternatives are used, employees should wash their hands (or other affected areas) with soap and running water as soon as possible.

Factors Responsible for Poor Results

Mechanical problems such as:

- Malfunctioning equipment
- Machine not clean
- Cuvettes past expiration date or left exposed to air

Poor collection technique, such as:

- Not thoroughly drying the site prior to puncture
- Milking the site
- Not wiping away the first two to three drops of blood
- "Topping off" the cuvette with additional blood, resulting in air bubbles or layers in the cuvette
- Not filling the cuvette entirely
- Leaving the filled cuvette out of hemoglobin machine more than 10 minutes before measuring

Chapter 5. Staff Evaluation

Policy

All staff members performing blood tests will be trained in WIC University 101 through ADHS Office of Chronic Disease Prevention & Nutrition Services as a minimum requirement and authorized as competent before they perform any patient/client testing. They may also receive training at the local agency by the laboratory director or his/her designee.

All appropriate WIC staff will undergo mandatory training on capillary techniques and use of the HemoCue® equipment every two years, as arranged by the local WIC agency.

Additionally, all WIC staff referred to above will complete the ADHS Anemia CD-ROM module every two years and score at least 70% as a passing grade. Documentation of module completion will be maintained in the employee's training file.

This same staff must be continuously monitored to ensure proper implementation of the policies and procedures regarding blood collection, analysis, and quality assurance.

Procedure

For agencies that have local agency-provided training, the following procedure is suggested:

1. The laboratory director or designee will observe each staff member performing each step of collection procedures as outlined on the Staff Competency Check List, Appendix C.

2. The steps must be performed in an initial and follow-up practice session prior to clinical practice.

3. When a step has been completed correctly, the supervisor will place a check mark (√) in the appropriate box.

4. When a rating of 100% is obtained, the staff member is re-evaluated in two weeks. If a rating of 100% is not obtained, the staff member will be re-evaluated at one-week intervals until the 100% rating has been obtained.

5. Two consecutive ratings of 100% should be attained prior to authorization to perform patient/client testing.

6. All staff members authorized to perform blood testing should be monitored on the procedure quarterly.

Chapter 6. Administration of HemoCue® Data Management Equipment for the Local Agencies

Equipment	All docking stations, analyzers, and cuvettes will be provided through ADHS. Purchase of lancets are the responsibility of the local agency. See chapter two for recommended lancet sizes.
Receiving a New or Loaner Analyzer and Adding it to the Data Management System	Upon receipt of a new or loaner analyzer: 1) Place the new analyzer in the docking station and turn the analyzer on. This facilitates communication between the new analyzer so it will be recognized in the software at the state level. Leave the analyzer in the docking station for at least 15 minutes. 2) The Local Agency HemoCue® lead will contact the Community Services Team Administrative Assistant at the state to provide the serial number of the new analyzer. 3) The State staff will send the corresponding user list and configuration to the analyzer in the software. 4) State staff will instruct the Local Agency HemoCue® lead to re-dock the analyzer to receive the data transfer. 5) The analyzer should now ask for an Operator ID and Participant ID. If during the data transfer there was a communication error, please call the state staff to troubleshoot the error.
Adding and Deleting Users	When new staff start at the local agency contact the state Community Services Team Administrative Assistant to add the new user to the HemoCue® operator list. Provide the state with the new user's name, indicate their role or title, and issue the operator ID number for state to input in the software. The Local Agency Director or HemoCue® Lead will maintain an inventory of staff and corresponding operator ID numbers. When staff are no longer employed in the local agency contact the state Community Services Team Administrative Assistant to delete the user from the HemoCue® data management system. Local Agencies must contact the state within one week of the termination of the employee.
Inventory Control - Equipment Returns or Replacements	The Local Agency administration or HemoCue® Lead will maintain current inventory of existing analyzers and docking stations at all clinics, including backup equipment not in use. Inventory should include a minimum of serial numbers and corresponding site locations. This will include any loaner equipment received from HemoCue® during repairs. Any changes in inventory will be immediately reported to the state. Each Local Agency will have a minimum of one spare analyzer on hand at all times. Some agencies will have more spares available based on their size. A small par of analyzers will also be available in the state OCDPNS warehouse for immediate needs. Robert Talbot with the state WIC IT team will be contacted directly in the event that a replacement docking station is needed.

Chapter 7. Problems with an Analyzer or Docking Station

Maintenance of the Analyzer

Analyzers in clinics with a docking station should be docked a minimum of once a week. Analyzers in satellite sites or clinics without docking stations should be taken to the nearest site with a docking station and docked once a month.

Analyzers should be cleaned as needed. Local Agencies will develop policies for maintaining cleanliness of the analyzer. Cleaning instructions can also be found in the HemoCue® *Instructions for Use* guide, chapter five.

Deleting Stored Data From an Analyzer

The HemoCue Hb201 DM Analyzer has the capacity to hold 4000 patient tests. When the analyzer reaches capacity it will display error code E26. Save the patient test results by placing the analyzer in the docking station to upload all data to the state software. The last data exchange can be confirmed by going to the data/charts icon on the main menu display of the analyzer and by selecting *View Download Exchange*. Upon confirmation of data exchange to the current date, stored data may then be deleted. Only a Supervisor can delete data from the analyzer.

Follow these steps to delete stored patient tests:

1) Select the data/charts icon from the main menu
2) You may be prompted to enter your 5–digit user ID
3) Select *Delete* from the Stored Data Menu options
4) Select PAT/STAT from the Review options
5) Confirm the From and To Dates to represent the date range interval for deletion and change as required
6) Push OK
7) Log out and turn off the analyzer
8) The analyzer will now be functional and no longer displaying the E26 error code

The Hb201 DM Analyzer also has the capacity to hold 250 QC Tests. A QC Test is performed every time the analyzer is turned on. When the QC Memory is full the analyzer will display error code E27. Dock the analyzer and confirm the data exchange as outlined above prior to deleting the QC data. Follow the same steps to delete the QC data, with the exception of selecting QC Test in step 4 from the Review options.

Problems with an Analyzer or Docking Station Continued

Chain of Support for Troubleshooting

The following chain of support should be followed when resolving challenges with the DM Analyzer:
1st Contact – Site Supervisor
2nd Contact – Site Supervisor or Local Agency HemoCue Lead will call the state Community Services Team Administrative Assistant to report the problem. The state contact will walk the Local Agency through correcting the problem.
3rd Contact - If the problem requires additional attention the site will be instructed to contact Arizona's personal technical support with HemoCue®, Victor Hernandez at 1-800-881-1611, extension 128.

See Appendix D for contact names and phone numbers.

Protocols for Local Area Network Failures

A steady green light indicates that the docking station is fully charged and operational. A flashing green light indicates that the battery in the docked analyzer is charging.

A steady red light indicates an internal communication error within the docking station. A flashing red light indicates an external communication error. When receiving a red light, the Local Agency HemoCue® Lead will call Robert Talbot with the state WIC IT team to resolve the communication error with the docking station and the network.

In the event that a site experiences a problem with the analyzer or local area network and systems are temporarily down, staff will enter 99.5 as the Hgb value in AIM and document the network or analyzer failure in AIM. Analyzers can still perform patient tests even in the event of docking station connection failures.

Chapter 8. Glossary

Accuracy	The agreement of results with the true value for specimens measured.
Anemia	Hemoglobin concentration (or hematocrit) below the 5th percentile of the distribution of hemoglobin or hematocrit of healthy, well-nourished individuals of the same sex, age and stage of pregnancy.
Biohazard Bag/Container	A bag or container constructed of material of sufficient single thickness and strength to pass the 165-ram dropped dart impact resistant test as prescribed by STM D-1709-91 and certified by the bag manufacturer (usually red or orange and labeled "Biohazard").
Calibration	A means to determine the accuracy of an instrument by comparing it with a known standard. The HemoCue® Analyzer does a calibration "self-test" each time the analyzer is turned on.
CLIA ('88)	Clinical Laboratory Improvement Amendment of 1988 – a public law governing the operation of clinical laboratories in the U.S. and mandating that all laboratories must be regulated using the same standards regardless of the location, type or size.
Cuvette	A small transparent container in which solutions are placed for photometric analysis.
EPA-registered Disinfectant	A cleanser that is recognized by the Environmental Protection Agency as being effective against tuberculosis-causing bacteria as well as HIV & HBV. It is used to decontaminate work surfaces.
Hemoglobin	The main component of red blood cells. It serves as a vehicle for transportation of oxygen to the tissues and carbon dioxide from the tissues to the lungs.
Hemolysis	The destruction of red blood cell membrane causing release of hemoglobin into surrounding serum or plasma.
Iron Deficiency Anemia	A reduction in the number of red blood cells resulting from iron depletion as evidenced by other laboratory testing.

Glossary Continued

Lancet	A sharp metal needle or blade, often encased in plastic, which is used to puncture the skin in order to collect a blood sample. It is individually packaged to ensure sterility. OSHA requires it to be retractable or self-sheathing, disposable and used only once.
Milking	To press out, drain off, remove, or draw out blood as if by milking.
Rocking	A method used to increase blood circulation and flow to the skin puncture site by using a thumb or finger in a gentle rocking movement (lightly press the finger from the knuckle nearest the fingertip toward the end of the finger).
Sharps	A medical device or instrument such as a hypodermic needle, syringe, lancet, scalpel blade, cuvette, Pasteur pipette or broken glass that can cause a cut, puncture, or laceration.
Universal Precautions	A set of rules established by the CDC, and adopted by OSHA, to control infection from bodily fluids in the health care setting.
Standard Precautions	Guidelines that apply to blood, all bodily fluids, non-intact skin and mucous membranes; replace Universal Precautions and are to be used for the care of all patients since everyone is assumed to be infected and, therefore, a possible contaminating factor.
Vial	A small container with a lid, used especially for storing liquids.

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Appendices

Appendix A - Blood Work Requirements, Options and Referrals

Appendix A - Blood Work Requirements, Options and Referrals

Policy

7 CFR §246.7(e)(1) Determination of nutritional risk, and Nutrition Risk Sections of State Plan for Risk 201 for women, infants and children states that "At a minimum, . . a hematological test for anemia such as hemoglobin...shall be performed and/or documented at certification for applicants with no other nutritional risk present. For applicants with a qualifying nutritional risk factor present at certification, such test shall be performed and/or documented within ninety (90) days of the date of certification."

The Blood Work Rule effective January 18, 2000, states that liberalizing the timeframes of blood collection is based on WIC's track record of reducing anemia rates nationally and improving coordination of services. Arizona WIC recognizes that it has one of the highest rates of anemia nationally and has enthusiastically adopted parts of the blood work rule, which will reduce barriers to service without sacrificing data collection.

Special Note

Anemia (blood) screening is part of the WIC certification process (which may be obtained via referral) and is mandatory for participation. The only time blood testing may be waived is if there is a religious objection (i.e. Christian Scientist) or a medical reason (i.e. hemophilia) or if performing the test will cause physical harm to the participant and/or staff member. In this case, one (1) month of Food Instruments may be issued and the blood test will be attempted in one month at their next WIC visit. Thus, a person may not be certified without blood work data except when religious or medical reasons exist and this must be noted in their WIC record.

If blood work data is brought from an outside source within 90 days of certification, the actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being entered into AIM.

Appendix A - Blood Work Requirements, Options and Referrals

Category	Age Blood Work Required	Certification Blood Work Required	Exceptions to Certification Blood Work Required
Pregnant women	**N/A**	**1 blood test taken during pregnancy**	**Prenatal women can be certified without blood work if:** • **at least one qualifying nutritional risk is present at certification and** • **blood test is obtained within 90 days of certification**
Postpartum women	**N/A**	**1 blood test taken 4-6 weeks after end of pregnancy**	**None**
Breastfeeding women	**N/A**	**For women 6-12 months postpartum, no blood test is required if 1 test was taken after end of pregnancy**	**For women 6-12 months postpartum, no blood test is required if 1 test was taken after end of pregnancy**
Infants <9 months	**Not Required**	**Not Required**	**Not Required**
Infants 9 months or older	**Blood work required once between 9-12 months**	**Blood work required for infants certifying between 9-12 months**	**Blood work taken between 12-13 months can be used when no other blood work is available for infant category**
Children 12-24 months	**Blood work required once between 12-24 months (6 months after infant test)***	**Blood work required at initial certification** **All children are required to have blood work on an annual basis unless previous blood work result demonstrated nutritional risk eligibility for low Hgb. In this case, blood work is needed every 6 months.**	
Children 24-60 months	**N/A**		

***Blood work taken at or before the first birthday does not satisfy the requirement for both the infant blood work and the children's 12-24 month blood work. Separate blood work is required for each age range.**

Appendix A - Blood Work Requirements, Options and Referrals

Pregnant Women	Blood work must be collected during the pregnancy. Blood work is usually collected by WIC staff at the certification visit. Results from an outside source (i.e. doctor's office) are also acceptable if it was collected during the pregnancy. If the results are not available at the Certification appointment, a note must be placed in the chart outlining the method and date by which the results will be reported. In the interim, the participant is placed on monthly pick-up, pending provision of blood work, for up to 60 days. Women who are certified presumptively (with Risk 503) need to have blood work done within 90 days of certification. They will be screened for all risks in 60 days, including anemia screening, if no other risk is found.
Postpartum & Breastfeeding Women	Blood work must be collected during the postpartum period: Preferably within four to six weeks (30 - 45 days) after the termination of the pregnancy. Blood work is not valid if drawn before four weeks (30 days) postpartum. The second blood test for breastfeeding women should be approximately six months postpartum. This second test is optional for women who had normal results from previous certification. Blood work is usually collected by WIC staff at each certification visit. Results from an outside source (i.e., doctor's office) are acceptable if collected after four weeks postpartum and collected within 90 days of the certification date. This may be done only if another nutritional risk is present at the Certification appointment. The actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being recorded.

Appendix A - Blood Work Requirements, Options and Referrals

Infants

Blood tests are not required for infants under nine months of age. Blood work should be collected:

- Once between 9–12 months of age, and/or
- At the time of certification which begins after the infant has reached nine months of age.
- By WIC staff. Results from an outside source (i.e. doctor's office) are acceptable if drawn after nine months of age for a full-term infant or after six months of age for a premature infant. A blood test before nine months of age may also be appropriate for low birth weight infants who are not fed iron-fortified formula.
- If the blood is drawn at 12 months of age, the cutoffs used should be reflective of a one-year-old child status.

Children

Blood work must be done on all children at least once every 12 months after the child is 18 months old. The exception is if the blood work data was within normal limits (WNL) at or within their last certification, in which case, there may be a period of 14 months between blood tests. Children are at highest risk for anemia between 9 and 18 months of age.

- **Example**: Blood work taken at 10 months of age may be used to certify a 12 month old child. A blood test is required at the 15-18 month certification for all children.
- **Example**: A child's results were within normal limits (WNL) during the certification periods beginning at 12 months and 18 months. The test is optional at the 24-month certification.

Children 2-5 years old with low hemoglobin must have a blood test at six-month intervals. Blood work is usually collected by WIC staff at the Certification visit. Results from an outside source (i.e. doctor's office) are acceptable if drawn within 90 days of the certification date. The actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being recorded. If no risk can be found at a certification, a blood test should be performed before ruling that the child is ineligible, even if the child's last result was normal.

- **Exception:** If the authorized representative waives the blood test after having the consequences explained to them, the child is then ruled ineligible.

Appendix A - Blood Work Requirements, Options, and Referrals

Children Continued

If the local agency has closed priorities, a blood test is recommended before placing a child on the waiting list.

Certification of a child who is new to the program will include a blood test, regardless of the age of the child.

Exception: The certification of a child who is an out-of-state transfer does not require a blood test. If a hemoglobin value from the child's most recent certification that is within normal limits is available on the Verification of Certification (VOC), that value may be entered.

Recommended Procedures

For hemoglobin results below the "Anemia" cutoff value:
The Community Nutrition Worker (CNW) will educate the participant or caregiver that WIC screens for (not diagnoses) anemia and counsels the participant on appropriate strategies to increase their iron levels.

For hemoglobin results outside the "Nutritionist" range:
If a client's hemoglobin value is outside the "Nutritionist" range for the first time, perform the procedure again. If possible, have a different person run the test on a different puncture site, such as an alternate finger or the infant's other heel. Record the higher of the two values in the AIM system.
Educate the participant or caregiver that WIC screens for (not diagnoses) anemia and since their value is outside of WIC's normal range, they will be referred to the nutritionist for further evaluation.

If the hemoglobin value remains outside of the "Nutritionist" range at their subsequent Certification, the CNW will automatically refer them to their healthcare provider. This is documented in the Referral section of the Care Plan screen in the AIM system.

Note: Poor technique may result in an abnormally low value.

Appendix A - Blood Work Requirements, Options, and Referrals

Use of 99.X codes	The 99.X codes are only to be used as placeholders in the 'Hgb' field in the Medical screen of the AIM system. They are not to be used in the height or weight fields.
99.5	• The code 99.5 is to be used when blood work is pending. This indicates that the applicant is bringing the data from an outside source (i.e.: doctor's office). The applicant has ninety (90) days from the date of certification to bring in the data. • When 99.5 is entered, only one (1) month of Food Instruments are to be issued at a time. This can occur up to three (3) times. **A note must be entered into the Notes box in the Medical screen in AIM.** If the applicant does not bring in the data within ninety (90) days, they are to be terminated from the WIC Program. • When certifying postpartum women that are less than 4-6 weeks postpartum, a code of 99.5 should be used and one (1) month of Food Instruments should be issued. By their second postpartum WIC appointment, they will be able to have the blood work performed. • All applicants (except pregnant women) who have a 99.5 code for blood work must have another qualifying risk at the time of certification in order to be eligible for WIC Program benefits. Pregnant women can be certified as presumptively eligible for sixty (60) days, without a documented nutritional risk factor while their blood work is pending; blood work must be performed and a nutritional risk must be documented within sixty (60) days of certification.
99.6	The code 99.6 is used when hemophilia (a bleeding disorder found mostly in males) or a religious reason (i.e.: Christian Scientist) are present that prevent blood from being collected. **This must be documented in the Notes box in the Medical screen in AIM.**
99.7	The code 99.7 is to be used when blood work is not required at that certification (see table earlier in this Appendix). If a 99.7 code is used for a C2, C3, or C4 client, then there must be a normal hemoglobin result for the client, collected and recorded within less than one year. If a 99.7 code is used for a EN or PN, there must be a normal hemoglobin result for the client, collected and recorded when the women was four (4) or more weeks postpartum. If a 99.7 code is used for a C1, PG1 or PG2 client, there must be a normal hemoglobin result for the client, collected and recorded within less than five (5) months. For pregnant women, the normal hemoglobin result on record must have been collected during the current pregnancy.
99.8	The code 99.8 is used in situations where drawing blood will create a safety hazard to the client or the WIC staff member. This is not used in the case of HIV/AIDS, since staff should always use Universal Precautions (UP; see page 2) to protect themselves. **The reason this code was used must be documented in the Notes box in the Medical screen in AIM.**

Appendix B – CDC Cutoffs for Anemia

Cutoff values for Hemoglobin Levels at 0-2,999 feet

Smoking Status	action	Pregnant						Breastfeeding/Post-Partum				Infant and Child			
		1st Trimester 0 – 13 weeks		2nd Trimester 14 – 26 weeks		3rd Trimester 27 + weeks		12 years to 14 years 11 months		15 years +		Infant 6 to 23 months		Child 2 to 5 years	
Non-Smoker	Anemia	**10.9**		**10.4**		**10.9**		**11.7**		**11.9**		**10.9**		**11.0**	
	Nutritionist	8.5	16.3	8.1	15.9	8.5	16.3	9.2	17.0	8.8	16.6	7.9	15.7	8.2	16.0
up to 1 pack (1-19 cigarettes)	Anemia	**11.2**		**10.7**		**11.2**		**12.0**		**12.2**					
	Nutritionist	8.8	16.6	8.3	16.1	8.8	16.6	9.5	17.3	9.4	17.2				
1-2 packs (20-39 cigarettes)	Anemia	**11.4**		**10.9**		**11.4**		**12.2**		**12.4**					
	Nutritionist	9.5	17.3	7.9	15.7	9.5	17.3	9.7	17.5	9.9	17.7				
2+ packs (40+ cigarettes)	Anemia	**11.6**		**11.1**		**11.6**		**12.4**		**12.6**					
	Nutritionist	10.2	18.0	7.5	15.3	10.2	18.0	9.9	17.7	10.4	18.2				

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 3,000-3,999 feet

Smoking Status	action	Pregnant						Breastfeeding/Post-Partum				Infant and Child			
		1st Trimester 0 – 13 weeks		2nd Trimester 14 – 26 weeks		3rd Trimester 27 + weeks		12 years to 14 years 11 months		15 years +		Infant 6 to 23 months		Child 2 to 5 years	
Non-Smoker	Anemia	**11.1**		**10.6**		**11.1**		**11.9**		**12.1**		**11.1**		**11.2**	
	Nutritionist	9.0	16.8	8.6	16.4	9.0	16.8	9.4	17.2	9.3	17.1	8.3	16.1	8.7	16.5
up to 1 pack (1-19 cigarettes)	Anemia	**11.4**		**10.9**		**11.4**		**12.2**		**12.4**					
	Nutritionist	9.3	17.1	8.8	16.6	9.3	17.1	9.7	17.5	9.8	17.6				
1-2 packs (20-39 cigarettes)	Anemia	**11.6**		**11.1**		**11.6**		**12.4**		**12.6**					
	Nutritionist	10.0	17.8	8.4	16.2	10.0	17.8	9.9	17.7	10.3	18.1				
2+ packs (40+ cigarettes)	Anemia	**11.8**		**11.3**		**11.8**		**12.6**		**12.8**					
	Nutritionist	10.7	18.5	8.0	15.8	10.7	18.5	10.1	17.9	10.8	18.6				

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 4,000-4,999 feet

Smoking Status	action	Pregnant						Breastfeeding/Post-Partum				Infant and Child			
		1st Trimester 0 – 13 weeks		2nd Trimester 14 – 26 weeks		3rd Trimester 27 + weeks		12 years to 14 years 11 months		15 years +		Infant 6 to 23 months		Child 2 to 5 years	
Non-Smoker	Anemia	**11.2**		**10.7**		**11.2**		**12.0**		**12.2**		**11.2**		**11.3**	
	Nutritionist	9.1	16.9	8.8	16.6	9.1	16.9	9.5	17.3	9.4	17.2	8.4	16.2	8.8	16.6
up to 1 pack (1-19 cigarettes)	Anemia	**11.5**		**11.0**		**11.5**		**12.3**		**12.5**					
	Nutritionist	9.4	17.2	9.0	16.8	9.4	17.2	9.8	17.6	9.9	17.7				
1-2 packs (20-39 cigarettes)	Anemia	**11.7**		**11.2**		**11.7**		**12.5**		**12.7**					
	Nutritionist	10.2	18.0	8.6	16.4	10.2	18.0	10.0	17.8	10.4	18.2				
2+ packs (40+ cigarettes)	Anemia	**11.9**		**11.4**		**11.9**		**12.7**		**12.9**					
	Nutritionist	10.9	18.7	8.2	16.0	10.9	18.7	10.2	18.0	10.9	18.7				

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 5,000-5,999 feet

Smoking Status	action	Pregnant						Breastfeeding/Post-Partum				Infant and Child			
		1st Trimester 0 – 13 weeks		2nd Trimester 14 – 26 weeks		3rd Trimester 27 + weeks		12 years to 14 years 11 months		15 years +		Infant 6 to 23 months		Child 2 to 5 years	
Non-Smoker	Anemia	**11.4**		**10.9**		**11.4**		**12.2**		**12.4**		**11.4**		**11.5**	
	Nutritionist	9.3	17.1	8.9	16.7	9.3	17.1	9.7	17.5	9.5	17.3	8.5	16.3	8.9	16.7
up to 1 pack (1-19 cigarettes)	Anemia	**11.7**		**11.2**		**11.7**		**12.5**		**12.7**					
	Nutritionist	9.6	17.4	9.2	17.0	9.6	17.4	10.0	17.8	10.1	17.9				
1-2 packs (20-39 cigarettes)	Anemia	**11.9**		**11.4**		**11.9**		**12.7**		**12.9**					
	Nutritionist	10.3	18.1	8.8	16.6	10.3	18.1	10.2	18.0	10.6	18.4				
2+ packs (40+ cigarettes)	Anemia	**12.1**		**11.6**		**12.1**		**12.9**		**13.1**					
	Nutritionist	11.0	0.0	8.4	16.2	11.0	18.8	10.4	18.2	11.1	18.9				

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 6,000-6,999 feet

Smoking Status	action	Pregnant						Breastfeeding/Post-Partum				Infant and Child			
		1st Trimester 0 – 13 weeks		2nd Trimester 14 – 26 weeks		3rd Trimester 27 + weeks		12 years to 14 years 11 months		15 years +		Infant 6 to 23 months		Child 2 to 5 years	
Non-Smoker	Anemia	**11.6**		**11.1**		**11.6**		**12.4**		**12.6**		**11.6**		**11.7**	
	Nutritionist	9.4	17.2	9.1	16.9	9.4	17.2	9.9	17.7	9.7	17.5	8.7	16.5	9.1	16.9
up to 1 pack (1-19 cigarettes)	Anemia	**11.9**		**11.4**		**11.9**		**12.7**		**12.9**					
	Nutritionist	9.7	17.5	9.3	17.1	9.7	17.5	10.2	18.0	10.2	18.0				
1-2 packs (20-39 cigarettes)	Anemia	**12.1**		**11.6**		**12.1**		**12.9**		**13.1**					
	Nutritionist	10.5	18.3	8.9	16.7	10.5	18.3	10.4	18.2	10.7	18.5				
2+ packs (40+ cigarettes)	Anemia	**12.3**		**11.8**		**12.3**		**13.1**		**13.3**					
	Nutritionist	11.2	19.0	8.5	16.3	11.2	19.0	10.6	18.4	11.2	19.0				

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 7,000-7,999 feet

Smoking Status	action	Pregnant						Breastfeeding/Post-Partum				Infant and Child			
		1st Trimester 0 – 13 weeks		2nd Trimester 14 – 26 weeks		3rd Trimester 27 + weeks		12 years to 14 years 11 months		15 years +		Infant 6 to 23 months		Child 2 to 5 years	
Non-Smoker	Anemia	**11.9**		**11.4**		**11.9**		**12.7**		**12.9**		**11.9**		**12.0**	
	Nutritionist	9.6	17.4	9.3	17.1	9.6	17.4	10.2	18.0	9.8	17.6	8.8	16.6	9.2	17.0
up to 1 pack (1-19 cigarettes)	Anemia	**12.2**		**11.7**		**12.2**		**13.0**		**13.2**					
	Nutritionist	9.9	17.7	9.5	17.3	9.9	17.7	10.5	18.3	10.4	18.2				
1-2 packs (20-39 cigarettes)	Anemia	**12.4**		**11.9**		**12.4**		**13.2**		**13.4**					
	Nutritionist	10.6	18.4	9.1	16.9	10.6	18.4	10.7	18.5	10.8	18.6				
2+ packs (40+ cigarettes)	Anemia	**12.6**		**12.1**		**12.6**		**13.4**		**13.6**					
	Nutritionist	11.3	19.1	8.7	16.5	11.3	19.1	10.9	18.7	11.3	19.1				

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Appendix C - Staff Competency Check List

Staff Name:_____

Supervisor:_____

Completed = √
Not met = ⃠
Grade = # of √ ÷ 16 x 100 =___%

PROCEDURE	#1	#2	#3	COMMENTS
1. Identify client				
2. Assemble supplies				
3. Cleanse & glove hands				
4. Position client & choose site				
5. Warm site (if necessary)				
6. Cleanse puncture site and dry				
7. Hold site firmly & pull skin taut				
8. Puncture skin (correct site and depth)				
9. Wipe off first 2-3 drops (no milking)				
10. Cuvette tip pointed down, filled in one step (no bubbles or layers)				
11. Apply pressure & bandage (if appropriate)				
12. Wipe excess blood from outside of cuvette				
13. Correctly dispose of used supplies				
14. Remove & dispose of gloves, cleanse hands				
15. Record results				
16. Clean surface				

Scores = ___ ___ ___ → Avg. Score ___

Staff Signature_____Date:_____

Supervisor Signature_____Date:_____

Appendix D – Contact List

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Appendix E – Analyzer Entry Error Log

HemoCue Analyzer Client ID Entry Error Log

Date	Clinic	Client Name	Correct Client ID	Incorrect Client ID Entered	Hgb Value